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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,698	02/03/2005	Yasuyoshi Ueda	5404/81	2912

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EXAMINER	
SINGH, SATYENDRA K	
ART UNIT	PAPER NUMBER
1657	
MAIL DATE	DELIVERY MODE
11/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,698	UEDA ET AL.	
	Examiner	Art Unit	
	SATYENDRA K. SINGH	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *1,2,4,8,12,13,15,17,20 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,31,33,34,36,39-41,46,49,51,61-67 and 69-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/27/08; 6/10/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,8,12,13,15,17,20,28,29,31,33,34,36,39-41,46,49,51,61-67 and 69-77.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 25th 2008 has been entered.

Claims 1, 2, 4, 8, 12, 13, 15, 17, 20, 28, 29, 31, 33, 34, 36, 39-41, 46, 49, 51, 61-67 and 69-77 are pending in the application. Claim 68 has been canceled by applicant's current amendment to claims.

Claims 29, 31, 33, 34, 36, 39-41, 46, 49, 51, 61-67 and 69-77 (the elected invention of group III, as currently amended) are examined on their merits in this office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 63 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

possession of the claimed invention. Claim 63, as currently amended, recites the limitation "*wherein a weight ratio of the **fat or oil** to a total weight of **fat or oil and polyol** is not lower than 1/10 when the fat and oil and the polyol exist together*", which does not have an explicit support in the specification as filed. Applicant's remarks (see page 9, in particular) fail to point out the appropriate support for this amendment in the claim. The specification (on page 24, lines 28-34) states the following in this regard:

> "In the composition mentioned above, the proportions of the fat and oil and polyol is not particularly restricted but, in view of the solubility of coenzyme Q10, the weight ratio **fat and oil/(fat and oil + polyol)** is generally not lower than 1/10, preferably not lower than 1/5, more preferably not lower than 1/2, still more preferably not lower than 2/3. It goes without saying that the polyol-free case is also appropriate"

It is noted that such disclosure fails to support the subject matter of claim 63 as currently presented because the instant claim requires a weight ratio of the "fat or oil" to a total weight of "fat or oil" and polyol, which is not lower than 1/10 "when the **fat and oil and polyol** exist together". Since, the claimed invention is not fully supported by the disclosure either in the narrative or generic or in the examples or in the original claims provided by applicants, the claimed limitation constitutes a **new matter** situation. Appropriate explanation/correction is required.

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 29, 31, 33, 34, 36, 39-41,46, 49, 51 and 61-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 29

recites the limitation of "**fat and oil**" without providing any explicit definition of the term in the instant disclosure (see specification, pages 5-8, in particular) as to how to interpret this limitation as presented in the invention as claimed. Similarly, claim 62 seems to recite said limitation "fat and oil" in an unclear Markush group containing various exemplifications that includes various types of oils and variety of different fats, which result in the claimed invention being indefinite. It is not clear if the term "fat and oil" is one component of the composition as claimed, or it requires both fat as well as oil. Appropriate correction is required.

In the absence of any explicit definition of said term, instant claims have been interpreted (for the term "fat and oil") as being met by the presence of any one of the two recited components (i.e. fat or oil) found in a composition in the prior art.

Response to Applicant's Arguments

Applicant's arguments (see remarks, page 9, 3rd paragraph, in particular) regarding the use of term "fat and oil" that "*One skilled in the art readily understands the meaning of the term "fat and oil", a term which in English usage has the same meaning as the term "oil and fat". In the context of this discussion, the phase, "when the fat and oil and the polyol exist together" is added in claim 63. As such, claim 63 serves to clarify the meaning(s)*" is duly noted. However, it is not clear from the instant disclosure as filed, if the term represents fat, oil or both. In addition, it is not clear as to how one of ordinary skill in the art would interpret the recitation of claim 63, which applicant argues "serves to clarify the meaning(s)" of the term "fat and oil" because instant claim as

currently amended recites limitation of a weight ratio wherein the component(s) recited are optional. Appropriate explanation/correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names **joint inventors**. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 29, 31, 33, 34, 36, 39-41, 46, 49, 51, 61-67 and 69-77 (as currently amended) are rejected under 35 U.S.C. 103(a) as being unpatentable over Chopra (WIPO document, WO 01/52822 A1; IDS) in view of Motoyama et al (US 4,751,241; [A]).

Claims as amended are directed to a "reduced coenzyme Q10-containing composition which comprises reduced coenzyme Q10, a polyglycerol fatty acid ester, and a fat and oil (in the absence of an

explicit definition of the term in the instant specification, taken as either fat or oil) and/or a polyol, wherein the content of the polyglycerol fatty acid ester is not higher than 50% by weight based on total weight of the composition minus a weight of coenzyme Q10" (see instant claims for detailed recitations).

Chopra (IDS) discloses a reduced coenzyme Q10-containing composition (see abstract, claims, and examples I-X, in particular) comprising reduced coenzyme Q10, a fat or oil, and a polyol (such as glycerol or other polyhydric alcohols). Chopra discloses reduced coenzyme Q10-containing compositions in various forms including oral dosage forms such as soft capsules, etc. which are "substantially ubiquinone-free", and incorporate reducing agents, oils or fat, polyols, and surfactants (see WIPO document, page 14, 5th paragraph, and examples I-X, in particular). Chopra discloses that such compositions may contain soybean oil, sunflower oil, safflower oil, rapeseed oil, fish oil, medium chain triglycerides, phospholipids (as recited in instant claim 62; see Chopra, various embodiments), surfactants (such as Tween or Span; see examples I, III, IV, VI, in particular), reducing agent such as vitamin C or ascorbyl palmitate (see Chopra, examples, and claim 2, in particular), and can be prepared or stored in a deoxygenated (such as prepared and sealed under nitrogen gas; see Chopra, page 21, example I, last paragraph, in particular).

However, a reduced coenzyme Q10-containing composition comprising **polyglycerol fatty acid ester,** wherein the content of the polyglycerol fatty acid ester is not higher than 50% by weight based on total weight of the composition minus a weight of coenzyme Q10 (as specifically recited in instant claims 70-72; **diglycerol monooleate**) is not explicitly taught by the composition of Chopra (IDS).

Motoyama et al [A] discloses polyglycerol fatty acid esters (see abstract, summary of the invention, columns 1-2, in particular) such as diglycerol monooleate (see column 2, lines 23-30, in particular) to be used as emulsifying agents for drugs that are very slightly soluble in water (including ubiquinones, CoQ10; see column 2, lines 38-

56, in particular) in order to enhance the absorption and thus bioavailability of said drugs (i.e. in a pharmaceutical composition) in the digestive tract when administered using oral dosage forms such as soft capsules (see columns 4-5, and examples), and wherein the content of polyglycerol fatty acid ester used in the composition for increasing the dispersibility of the drug is usually 0.05~30 parts by weight for one part by weight of the drug (see column 4, lines 53-56, and last paragraph; and examples, in particular).

Therefore, it would have been obvious to a person of ordinary skill in the pharmaceutical composition art to modify the reduced coenzyme Q10-containing composition of Chopra (IDS) such that it contains (in addition to the surfactants such as Tween or Span) an emulsifying agent such as polyglycerol fatty acid ester as explicitly taught and exemplified by Motoyama et al.

One of ordinary skill in the art would have been motivated at the time of invention to make such modification in the composition taught by Chopra (IDS) in order to obtain a better reduced coenzyme Q10-containing composition (having an enhanced absorption and bioavailability in the gut) as suggested by Motoyama et al, with a reasonable expectation of success. The limitations, "wherein the content of the polyglycerol fatty acid ester is not higher than 50% by weight based on total weight of the composition minus a weight of coenzyme Q10" would have been obvious to a person of ordinary skill in the art at the time this invention was made as Motoyama et al disclose the suitability of a broad range of concentrations that can be used with a drug that is very slightly soluble in water (such as Co-Q10) in order to improve its

dispersibility and thus its bioavailability owing to the surface active properties of said polyglycerol fatty acid esters (see column 4, lines 38-42, in particular) when combined with the composition as claimed. The scope of the claimed subject matter, as currently presented by applicants, fails to patentably distinguish over the state of the art as represented by the cited prior art references of record. Therefore, the claims are properly rejected under 35 U.S.C. § 103(a).

With regard to the limitations of claims 33 (content of fat and oil and/or polyol, on percent basis), 36 (content of ascorbic acid, on percent basis), 41 (the content of surfactant), 63 (ratio of fat and oil to fat and oil and polyol by weight), 64 (content of reduced CoQ10, on percent basis), and 67 (the content of polyglycerol fatty acid ester by weight, on percent basis), it is to be noted that given the detailed disclosures of all the components and their amounts used for various preparations or dosage forms by Chopra and Motoyama et al (as discussed above), the adjustments to the contents and ratio of various components used in the composition would have been obvious to a person of ordinary skill in the pharmaceutical formulation art, and would involve routine optimization in order to achieve a better and stable composition containing reduced Coenzyme Q10. The claimed limitations of instant claims 46, 49, 51 and 69 are taken to be intrinsic to the composition taught by the cited prior art references, as discussed above.

As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Response to Applicant's Arguments

Applicant's arguments filed with the office on July 7th 2008 (as they pertain to the prior art rejection of record) have been fully considered but they are not persuasive for the following reasons of record.

It is to be noted that instant claims are directed to a composition comprising a "*reduced coenzyme Q10, a polyglycerol fatty acid ester, and a fat and oil and/or polyol, wherein the content of the polyglycerol fatty acid ester is not higher than 50% by weight based on total weight of the composition minus a weight of coenzyme Q10*" (see amended claim 29, in particular).

Applicant's argument regarding 103(a) rejection (see remarks, pages 9-10, in particular) is fully considered but is not found to be persuasive because claim 29, as amended, does not require the limitations of surfactants and/or ascorbic acid for the composition as claimed and as currently argued by applicants. The argument that Motoyama et al does not teach reduced coenzyme Q10 formulation (see remarks, page 10, last paragraph, in particular) is not found to be persuasive because Motoyama et al was relied upon to demonstrate the fact that the concept of using or incorporating polyglycerol fatty acid esters (such as diglycerol monooleate) along with drug formulations that are very slightly soluble in water (including coenzyme Q10) and require said polyglycerol fatty acid esters in order to provide better dispersibility and thus bioavailability (see Motoyama et al, column 5, 2nd paragraph, in particular) was well known in the art at the time the claimed invention was made. The argument that Motoyama et al "*neither discloses nor suggest the effect of the present invention*" (see

page 11, 1st paragraph, in particular) is not found to be persuasive because all the components as recited in the claimed composition (i.e. the product as claimed) are explicitly taught and/or suggested and made obvious by Chopra when taken in combination with the disclosure of Motoyama et al, and therefore, in absence of any evidence to the contrary, the composition as claimed remains rejected over the cited prior art references of record under 35 USC 103(a).

Obviousness-type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 29, 31, 33, 34, 36, 39-41, 46, 49, 51, 61-67 and 69-77 (as currently amended) **are** provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-19 of copending Application No. 11/586,511 (filed in US on 10/26/2006; common inventors; and same assignee, Kaneka Corporation, Japan). Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application also claims a reduced coenzyme Q10-containing composition (processed as an oral dosage form) comprising reduced coenzyme Q10, oil and fat, a polyglycerol fatty acid ester, along with a reducing agent, ascorbic acid. Since the two sets of composition claims are very similar (i.e. co-existent) in their scope, an obviousness-type double patenting rejection is required.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to ODP Arguments

Applicant's arguments regarding the ODP rejection of record have been fully considered but they are not persuasive for the following reasons of record. Applicants argue the following (see page 11, last paragraph):

> "Finally, with respect to obviousness-type double patenting, by the above amendments the claim 29 of the present invention is not generic to the claim 16 of co-pending application 11/586,511. Therefore, the obviousness-type, double patenting rejection should also be withdrawn"

In response, it is noted that claim 29 of the instant application is directed to a reduced coenzyme Q10-containing composition comprising reduced coenzyme Q10, a polyglycerol fatty acid ester, and a fat and oil and/or a polyol, which is deemed generic to the claim 16 of the co-pending application 11/586,511 because said claim 16 recites the limitation of "polyglycerol fatty acid ester with a polymerization degree of glycerol being not lower than 3 and/or a condensed ricinoleic acid polyglyceride", and therefore, the two sets of claims are deemed co-extensive in scope, and thus, the provisional ODP rejection of record is properly made.

Conclusion

NO claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SATYENDRA K. SINGH whose telephone number is (571)272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sandra Saucier/
Primary Examiner, Art Unit 1651

/Satyendra K. Singh/
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